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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/706,045	11/03/2000	Julie Straub	ACU 109 DIV(2)	7016

7590

10/24/2002

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EXAMINER

WEBMAN, EDWARD J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 10/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/706045

Applica

STRAUB

Examiner

WEBMAN

Group Art Unit

1617

--The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address--

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 7/12/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 23-35 is/are pending in the application.
- ☒ Of the above claim(s) 26-28, 30-32 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 23-25, 29, 33-35 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Applicant Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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3/23/03
Applicant's election of ~~parental~~^{te} in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out any errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 23-25, 29, 33-35 rejected under 35 U.S.C. 102(e) as being anticipated by Gombotz et al.

Gombotz et al teach microspheres made by a process comprising dissolving an active to which is added a surfactant, after which the solvent is removed (Example I, column 11). Addition of Pore formers is disclosed (column 9, lines 51-55). Addition of sucrose is specified (column 9, line 65). An aqueous injection vehicle is disclosed (column 15, lines 49-50). Microspheres as small as one micron are specified (column 8, line 25).

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²
Parenteral, including subcutaneous delivery is disclosed (Abstracts).

As to the claimed drug particle size, it must be within the size of the microsphere within which it is contained. As to the claimed drug particle TAP density and surface area they must be possessed by the Gombotz et al composition in view of the presence of a pore former.

Claims 29 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 29 "suitable" is vague; it is unclear as to whether parenteral delivery is definitely claimed. "Solution" is indefinite because the composition is particulate.

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is 308-4432. The examiner can normally be reached on Monday-Friday from 9 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.


Webman/dl

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October 2, 2002


EDWARD J. WEBMAN
PATENT EXAMINER
GROUP 1500